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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,648	01/29/2004	James A. Hoxie	53893-5046-00	6515

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,648	HOXIE ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 6, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *6,8,9,11,14,15 and 17-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,10,12,13 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/7/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received October 6, 2006.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-16, HIV-2, deletion of V3 region \, SEQ ID NO: 11, and mutation of amino acid position 393.

Applicant argues that Examiner has not provided any reason or rationale regarding the imposition of the mutation restriction. In response Examiner points out that searching all mutations recited in the claims would require separate amino acid sequence searches for each and every mutation, because each mutation represents a different amino acid sequence. Whether the prior art search would reveal the mutants of SEQ ID NO: 11 or not, as pointed by the Applicant, it would be an undue burden for the Office to go over all possible hits and figure out if the sequences obtained from the search results of SEQ ID NO: 11 match any of the 22 mutations recited in the claims. In order to find prior art of all mutant sequences, a separate search for 22 different sequences is required. Besides that the mutant sequences have different structures, the mutations may result in different function of the polypeptide sequence. Thus as discussed above, it would be burdensome to search all mutant sequences together. Therefore the restriction is deemed proper and is made FINAL.

Claims 6, 8, 9, 11, 14, 15, and 17-72 are with drawn because they are drawn to a non-elected invention.

Claims 1-5, 7, 10, 12, 13, and 16 are under examination.

Priority

Acknowledgment is made for priority to a provisional Application 60/443,364, however the 60/443,364 Application does not disclose limitations of claims 4-16 such as the SEQ ID NO: 5 or SEQ ID NO: 11. For this reason claims 4-16 are given priority date of January 29, 2004.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 11, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7, 10, 12, 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a mutant of mammalian immunodeficiency virus glycoprotein gp120 polypeptide. The metes and bounds of the "mutant" are not clear. The specification defines mutants as peptides, which may be altered in one or more amino acids. The specification does not define the type of alteration to be made in order to obtain a mutant of the mammalian immunodeficiency virus glycoprotein gp120 polypeptide. A mutant of mammalian immunodeficiency virus glycoprotein gp120 polypeptide could be any sequence of gp120 glycoprotein with amino acid deletions, substitutions, or

additions. It is not clear what are the metes and bounds of the claimed mutant, i.e. what is the amino acid sequence of the claimed mutant. Clarification is required.

Claims 1-5, 7, 10, 12, 13, and 16 are also indefinite for reciting the term "derivative". The term "derivative" is not one that has a universally accepted meaning in the art nor is it one that has been adequately defined in the specification. The primary deficiency in the use of this phrase is the absence of an ascertainable meaning for said phrase. Since it is unclear how the mammalian immunodeficiency virus glycoprotein gp120 polypeptide is to be derived to yield the class of derivatives referred to in the claims, there is no way for a person of skill in the art to ascribe a discrete and identifiable class of compounds to said phrase. Further, it is not clear whether the "derivative" the mammalian immunodeficiency virus glycoprotein gp120 polypeptide is formed by attachment of a detectable marker, therapeutic molecule, some other molecule or by altering the amino acid sequence, for example. The specification defines derivatives as peptides, which may be altered in one or more amino acids or nucleic acids. The specification does not define the type of alteration to be made in order to obtain a derivative of the mammalian immunodeficiency virus glycoprotein gp120 polypeptide. In absence of a single defined art recognized meaning for the phrase and lacking a definition of the term in the specification, one of skill in the art could not determine the metes and bounds of the claims. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 10, 12, 13, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated nucleic acid encoding a mammalian immunodeficiency virus glycoprotein gp120 polypeptide or fragment thereof. The specification contemplates generation of fragments of mammalian immunodeficiency virus glycoprotein (see [0207]).

"As used herein, the term "fragment" as applied to a polypeptide, may ordinarily be at least about seven contiguous amino acids, typically, at least about fifteen contiguous amino acids, more typically, at least about thirty contiguous amino acids, typically at least about forty contiguous amino acids, preferably at least about fifty amino acids, even more preferably at least about sixty amino acids and most preferably, the peptide fragment will be greater than about sixty contiguous amino acids in length."

However, the instant specification provides insufficient written description of the specific sequences encompassed by the claims. It is apparent that at the time when the current application was filed the Applicant did not have the possession of the claimed fragments of mammalian immunodeficiency virus glycoprotein gp120 polypeptide.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or

chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the specification contemplates production of fragments of mammalian immunodeficiency virus glycoprotein without providing an adequate written description of the claimed fragments. Based on the known sequence of the gp120 protein, one of skill in the art would not be able to identify the functional fragments of gp120 polypeptide. Applicant has not provided a core region of the claimed fragments that must be conserved in order for the gp120 fragment to retain desired properties. Accordingly, in the absence of insufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed structure of the encompassed genus of gp120 polypeptide fragments, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of production of genetically engineered monoclonal antibodies. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hasel et al. (US Patent 5,886,163). Claim is drawn to an isolated nucleic acid encoding a mammalian immunodeficiency virus glycoprotein gp120, or a mutant, derivative, or fragment thereof, wherein said gp120 polypeptide comprises a deletion of hypervariable loop 3 (V3), and further comprises a compensatory mutation. The current specification identifies a compensatory mutation as:

A "compensatory mutation" refers to one or more specific amino acids in a polypeptide sequence, where the identity of the amino acid(s) differs from that found at the same position(s) in the wild type polypeptide sequence, for the purpose or with the result of altering the properties and/or activity of the polypeptide in response to a second change affecting the properties and/or activity of the polypeptide."

Hasel et al. disclose a recombinant nucleic acid molecule, which encodes a mutant HIV-1 gp120 envelope glycoprotein comprising a V3 loop deletion, and a C4 domains point mutation (see the entire document, particularly claims 1-9, and the abstract). Thus by this disclosure Hasel et al. anticipate the current claims.

Conclusion

No claims are allowed. SEQ ID NO: 11 is free of prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB

Agnieszka Boesen, Ph.D.

12/20/06

Stacy B. Chen 12/21/06

STACY B. CHEN
PRIMARY EXAMINER